

***IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES***

Applicant: Philippe MSIKA

Title: COSMETIC METHOD FOR PREVENTING
AND/OR TREATING SKIN STRETCHMARKS,
AND USE IN DERMATOLOGY

Appl. No.: 10/808,701

Filing Date: 3/25/2004

Examiner: Gina C. YU

Art Unit: 1611

Confirmation No.: 6071

BRIEF ON APPEAL

Mail Stop Appeal Brief - Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Under the provisions of 37 C.F.R. § 41.37, this Appeal Brief is being filed together with the appeal fee of \$540.00 under 37 C.F.R. 41.20(b)(2). If this fee is deemed to be insufficient, authorization is hereby given to charge any deficiency (or credit any balance) to the undersigned deposit account 08-2025.

Applicants appeal the final rejection of claims 1-24 in the final Office Action dated October 6, 2009.

I. REAL PARTY IN INTEREST

The real party in interest is Laboratoires Pharmascience, the assignee of record, which is a French company that has merged with Laboratoires Expanscience, which has a principal place of business at 10, avenue de l'Arche, 92419 Courbevoie Cedex, France.

II. RELATED APPEALS AND INTERFERENCES

There is no related proceeding that will directly affect, be directly affected by or have a bearing on the present appeal, that is known to appellant, the assignee, or the appellant's patent representative.

III. STATUS OF CLAIMS

The present appeal is directed to claims 1-24, which are the claims under consideration (no claims are withdrawn). A copy of the pending claims 1-24 are attached herein in the Claims Appendix.

IV. STATUS OF AMENDMENTS

All amendments filed have been entered. There are no unentered amendments.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Among the claims on appeal, claims 1, 12, 13, 19, and 20 are independent.

Independent claim 1 relates to a method for reducing the formation of and/or treating skin stretchmarks in a person (page 2, lines 15-17), comprising applying to at least one area of skin comprising one or more stretchmarks a composition comprising, in a suitable vehicle, at least one soya peptide (page 2, lines 18-19).

Independent claim 12 relates to a method for reducing the formation of and/or treating skin stretchmarks in a person, comprising applying to at least one area of skin comprising one or more stretchmarks a composition comprising, in a suitable vehicle, at least one tripeptide consisting essentially of the amino residues glycine, histidine, and lysine (page 2, lines 15-20).

Independent claim 13 relates to a method for reducing the formation of and/or treating skin stretchmarks in a person, comprising applying to at least one area of skin comprising one or more stretchmarks and/or an at least one area liable to form stretchmarks, a composition comprising, in a suitable vehicle, (page 2, lines 15-18) at least one tripeptide having the sequence Gly-His-Lys, and the tripeptide is conjugated with acetic acid or acetate in the form of a complex with zinc (page 4, line 4 from bottom, to page 5, line 3).

Independent claim 19 relates to a method for reducing the formation of and/or treating skin stretchmarks in a person, comprising applying a composition to areas of skin liable to form stretchmarks or having stretchmarks (page 3, lines 1-3), the composition comprising, in a suitable vehicle, a mixture of at least one soya peptide and at least one tripeptide selected from tripeptides (page 2, lines 18-20) wherein the tripeptide has the sequence Gly-His-Lys, and the tripeptide is conjugated with acetic acid or acetate in the form of a complex with zinc (page 4, line 4 from bottom, to page 5, line 3).

Independent claim 20 relates to a method for reducing the formation of and/or treating skin stretchmarks (page 2, lines 1-9 from bottom) in a person, comprising applying to at least one area of skin comprising one or more stretchmarks and/or an at least one area liable to form stretchmarks (page 3, lines 1-3), a composition comprising, in a suitable vehicle, at least

one soya peptide (page 2, lines 18-20) and at least one tripeptide consisting essentially of the amino residues glycine, histidine, and lysine (page 4, lines 5-6 from bottom).

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection to be reviewed on appeal are as follows:

- Rejection of claims 1-6, 8-10, and 21-22 as obvious under 35 U.S.C. § 103(a) over U.S. Patent No. 5,444,091 ("Rapaport") and Frei et al., International J. of Cosmetic Science 20, 159-173 (1998) ("Frei").
- Rejection of claim 7 as obvious under 35 U.S.C. § 103(a) over Rapaport, Frei, and U.S. Patent No. 5,719,129 ("Andary").
- Rejection of claim 11 as obvious under 35 U.S.C. § 103(a) over Rapaport, Frei, and Flick, Cosmetic And Toiletry Formulations 1995 ("Flick").
- Rejection of claims 12-17 and 23-24 as obvious under 35 U.S.C. § 103(a) over Rapaport and DE 04244418 ("Quelle").
- Rejection of claim 18 as obvious under 35 U.S.C. § 103(a) over Rapaport, Quelle, and Flick.
- Rejection of claims 19-20 as obvious under 35 U.S.C. § 103(a) over Rapaport, Quelle, and Frei.

No other rejections are pending.

VII. ARGUMENT

The Office committed reversible error in finally rejecting claims 1-24 for the reasons that follow. Accordingly, the Office's final rejection of claims 1-24 should be reversed.

The Office erroneously relied on Rapaport's speculative statements as basis for asserting obviousness. The Office erred by failing to consider testimony in a Rule 132 Declaration (filed November 14, 2008, and included in the Evidence Appendix herein) providing strong evidence of nonobviousness over the art of record. By failing to consider the Declaration evidence, the Office erred in mischaracterizing Rapaport as disclosing that stretchmarks are treated by promoting the rigidity and elasticity of the skin.

The rejections on appeal are all based on obviousness. Obviousness is a question of law based on underlying factual inquiries, including determining the scope and content of the prior art, the differences between the claimed invention and the prior art; and the level of ordinary skill in the pertinent art. *KSR Int'l Co. v. Teleflex Inc.*, ___ U.S. ___, 82 U.S.P.Q.2d 1385, 1391 (2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1 (1966)).

"All words in a claim must be considered in judging the patentability of that claim against the prior art." M.P.E.P. § 2143.03, quoting *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

A. Rejection of claims 1-6, 8-10, and 21-22 as obvious over Rapaport and Frei.

The Office has finally rejected claims 1-6, 8-10, and 21-22 as obvious over Rapaport and Frei. In the final Office Action (page 2, line 11) the Office maintained this rejection "for the reasons of record", referring to the non-final Office Action dated December 23, 2008.

The Office relied on Rapaport for its disclosure of a "method of treating striae distensae lesions (stretchmarks) by topically applying to the affected skin a composition comprising alpha-hydroxy acids". Non-final Office Action dated December 23, 2008, page 2, lines 2-3 from bottom.

The Office conceded that Rapaport fails to teach a soya peptide. Non-final Office Action, page 3, lines 7-9.

To remedy this deficiency, the Office applied Frei, which according to the rejection, teaches that “soya peptide . . . increases skin firmness, elasticity, and tone.” The Office alleges that it would have been obvious “to modify the composition of Rapaport by incorporating soya peptide” because Rapaport “teaches that stretchmarks are treated by . . . promot[ing] the rigidity and elasticity of the skin” and “Frei teaches that soya protein stimulates collagen formation and elastin synthesis, thereby improving firmness and elasticity of skin” such that a “skilled artisan would have had a reasonable expectation of successfully improving the method of treating stretchmarks”. Non-final Office Action, page 3, lines 1-9 from bottom.

Applicants note that the Office did not allege any structural similarity between Rapaport’s compounds and Frei’ compounds or those of the present invention as claimed.

Responding to point 1 of the Declaration (“a person of ordinary skill in the art would not conclude from Rapaport that stretchmarks are treated by promoting the rigidity and elasticity of the skin”), the Office stated that Rapaport’s disclosure “should be considered objective teachings made available to one of ordinary skill in the art” and “whether a routineer would have doubted the publication is a subjective matter”. Non-final Office Action, page 8.

The Office must make factual findings supported by substantial evidence. In particular, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. ___, 82 U.S.P.Q.2d 1385, 1391 (2007).

Here, the Office has not met its burden to clearly articulate, in view of the Declaration testimony, why a person of ordinary skill in the art would have a “reasonable expectation of success” in combining Rapaport with Frei.

The Declaration states:

5. In my opinion, a person of ordinary skill in the art would not conclude from Rapaport that stretchmarks are treated by promoting the rigidity and elasticity of the skin. Rapaport speculates that alpha hydroxy acids reduce stretch marks by (i) eliciting a hyperplastic response in the epidermis and dermis that counters the breakdown of collagen, or (ii) by stimulating the production of interfibrillary material such as glycosaminoglycans which promotes both rigidity and elasticity to the skin. See Rapaport column 4, lines 31-38. Rapaport contains no test data supporting these assertions. These proposed mechanisms in Rapaport for enhancing skin elasticity and rigidity are unsupported. Consequently, a person of ordinary skill in the art would consider these mechanisms to be speculative and unproven.

Consequently, the Office erred in mischaracterizing Rapaport as disclosing that stretchmarks are treated by promoting the rigidity and elasticity of the skin. The Office erroneously relied on Rapaport’s speculation as basis for asserting obviousness.

Responding to point 2 of the Declaration (“a person of ordinary skill in the art reading Frei and Rapaport would not conclude that a soya peptide would be effective for treating stretchmarks”), the Office stated that “the declarant’s opinion that a skilled artisan would not have found motivation to make the present invention in view of the Frei disclosure is also viewed subjective” (non-final Office Action, page 8, last 3 lines).

To the contrary, the Declaration provides objective testimony based on Frei’s own statements expressing doubt. Regarding Frei, the Declaration states:

6. Frei provides no basis to infer that soya peptide increases skin firmness, elasticity, and tone. Frei does not directly state that soya peptide increases skin firmness,

elasticity, and tone. Frei describes a skin equivalent (SE) model, but Frei lacks any objective measurement of skin firmness, elasticity, and tone. Frei states “the application of soya peptide ... might ... delay the *in vitro* process of aging.” Frei, p. 171, 3d full para., last sentence (emphasis added). Frei further states “[t]his peptide is able to stimulate regeneration of metabolic activity, which may help the skin to look younger,” Frei, p. 171, 4th full para., last sentence (emphasis added). The use of “might” and “may” in the sentences quoted above indicates that the authors were uncertain of these assertions.

7. Frei is equivocal about soya peptide’s effect on ageing and recognizes that no definite conclusion is possible. Frei states “no conclusion could be drawn concerning the way the soya peptide acts in this SE model.” Frei, p. 171, first full paragraph, final sentence. In my opinion, a person of ordinary skill in the art reading Frei would not conclude that soya peptide increases skin firmness, elasticity, and tone.

The Office erred in failing to recognize the Declaration as record evidence (final Office Action, page 3, lines 13-16). Office personnel should consider all rebuttal arguments and evidence presented by applicants, and it is legal error not to consider evidence presented. M.P.E.P. § 2145, citing *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995) and *In re Alton*, 76 F.3d 1168 (Fed. Cir. 1996).


The following passage from Frei reveals why a person of ordinary skill in the art would consider speculative Frei’s statements relied on by the examiner (arrows indicate relevant sentences):

After 25 days of culture, the reconstituted epidermis showed some signs of ageing such as a reduction in the number of keratinocyte layers and a flatness of the basal membrane. However, after 15 days of soya peptide treatment, SEs present an epidermis which is morphologically closer to normal human skin than to control SEs. Keratinocyte renewal and differentiation has been strengthened by the application of soya peptide which might also delay the *in vitro* process of ageing.

On a study model which reproduces the environment in which dermal fibroblasts and keratinocytes develop *in vivo*, the significant stimulating effect of a soya peptide on extracellular matrix component synthesis and its action on epidermal differentiation have been shown clearly. This peptide is able to stimulate regeneration of metabolic activity, which may help the skin to look younger.

Frei, p. 171, 3d-4th paras. If “the application of soya peptide ... **might** ... delay the in vitro process of aging,” Frei, p. 171, 3d full para., last sentence (emphasis added), then the very same application **might** not. Similarly, if “[t]his peptide is able to stimulate regeneration of metabolic activity, which **may** help the skin to look younger,” Frei, p. 171, 4th full para., last sentence (emphasis added), then again, it **may** not. As a result, the evidence and explanation fail to support that “soya peptide ... increase[es] skin firmness, elasticity, and tone.”

Additionally, according to Frei, “no conclusion could be drawn concerning the way the soya peptide acts in this SE model.”

Although a significant protective effect of the epidermis in this SE model has been demonstrated in another study [25], because of its low molecular weight, the tested soya peptide may cross the epidermal barrier (*ex vivo* percutaneous absorption study and *in vivo* study, N. Abdul Malak and E. Perrier, unpublished paper). In addition no conclusion could also be drawn concerning the way the soya peptide acts in this SE model. 

Frei, p. 171, last sentence first full paragraph. This does not constitute the form of evidentiary support that the Office must show for asserting obviousness based on scientific theory. The M.P.E.P. states this requirement as follows:

2144.02 Reliance on Scientific Theory [R-6]

The rationale to support a rejection under 35 U.S.C. 103 may rely on logic and sound scientific principle. *In re Soli*, 317 F.2d 941, 137 USPQ 797 (CCPA 1963). However, when an examiner relies on a scientific theory, evidentiary support for the existence and meaning of that theory must be provided. *In re Grose*, 592 F.2d 1161, 201 USPQ 57 (CCPA 1979).

The Office erred by failing to provide the requisite evidentiary support for its scientific theory underlying the obviousness rejection, and the Office erred in failing to properly weigh the Declaration testimony providing strong evidence of nonobviousness over the art of record.

Consequently, the rejection over Rapaport and Frei should be reversed.

B. Rejection of claim 7 as obvious over Rapaport, Frei, and Andary.

This rejection should be reversed, because Andary does not cure the deficiencies of the combination of Rapaport and Frei, and because Andary's disclosure of a percent soya peptide in an anti-aging cream is inapposite.

Claim 7 is rejected as obvious over Rapaport and Frei further in view of US 5,719,129 ("Andary"). Claim 7 depends on claim 1, and incorporates all the limitations of this base claim. As explained above, claim 1 is patentable over Rapaport and Frei. Thus, the reasons mentioned above for claim 1, are also applicable here for claim 7. Furthermore, Andary disclosure of an anti-aging cream containing oraposide and 1% soya peptide does not fairly suggest that any particular percentage of soya peptide would be effective against skin stretchmarks. Thus, these three references in combination fail to render obvious claim 7, and the rejection should be reversed.

C. Rejection of claim 11 as obvious over Rapaport, Frei, and Flick.

This rejection should be reversed, because Flick does not cure the deficiencies of the combination of Rapaport and Frei with respect to claim 11.

Claim 11 was rejected as obvious over Rapaport and Frei further in view of Flick, Cosmetic And Toiletry Formulations 1995. Flick was asserted solely for its disclosure of an alpha hydroxy acid cream comprising 14.2 % of lactic acid (88%) that is formulated to pH of 3.5. A person of ordinary skill in the art would consider this disclosure irrelevant, because there is no clear basis to believe the pH of the Flick cream would be suitable for a cream used for treating stretchmarks. Thus, Flick cannot remedy the deficiencies of Rapaport and Frei, and this rejection should be reversed.

D. Rejection of claims 12-17 and 23-24 as obvious over Rapaport and Quelle.

The Office rejected claims 12-17 and 23-24 as obvious over Rapaport in view of Quelle.

The Office concedes that Rapaport fails to teach tripeptide consisting of the amino acids glycine, histidine, and lysine. Office Action, page 5.

To remedy these deficiencies, the Office applied Quelle, for its alleged disclosure that the “tripeptide Gly-His-Lys [is used] in cosmetic compositions to treat ageing skin and as radical scavenger (antioxidant).” Office Action, page 5.

This rejection is respectfully traversed, because it appears that the Office failed to consider the Declaration testimony on this issue, specifically points 3 and 4 of the Declaration (“the etiologies of skin ageing and striae distensae differ greatly” and “a product that stimulates collagen synthesis and elasticity of the skin is not sufficient to prevent or treat stretchmarks”). The Declaration states:

1. Rapaport and Frei relate to nonanalogous fields. Rapaport relates to treating striae distensae, while Frei relates to treating ageing skin (see respective Abstracts). Skin ageing and striae distensae have different etiologies. The physicochemical attributes of ageing skin are different from those for stretchmarks. For that reason, a person of ordinary skill in the art would not conclude that a formulation that is effective for treating the effects of ageing in skin would also be effective in treating stretchmarks (striae distensae).
2. Frei is not reasonably pertinent to the problem that Rapaport seeks to solve. Generally, the problems relating to ageing skin are not the same as the problems reflected in stretchmarks or striae distensae.
3. A person of ordinary skill in the art reading Frei and Rapaport would not conclude that a soya peptide would be effective for treating stretchmarks. Rapaport relates to treating lesions of striae distensae. See Abstract. Frei relates to treating skin ageing and states in the Abstract, “In this model, the soya peptide increased the thickness of the epidermis.” While that

effect may support anti-ageing properties, a person of ordinary skill in the art would not recognize effectiveness for treating stretchmarks.

The above Declaration testimony directly counters the Office's erroneous attempt to relate skin aging to the treating of stretchmarks. Thus, the rejection is improper and should be reversed.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. M.P.E.P. § 2143.03, quoting *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Claims 14-17 and 23, 24 depend on claims 12 or 13 and incorporate all their limitations. The dependent claims are therefore patentable for at least the same reasons mentioned above for claims 12 and 13.

E. Rejection of claim 18 as obvious over Rapaport, Quelle, and Flick.

Claim 18 was rejected as obvious over Rapaport, Quelle, and Flick. The rejection should be reversed, because claims 18 depends from patentable claim 13, which is allowable for the reasons stated above.

F. Rejection of claims 19-20 as obvious over Rapaport, Quelle, and Frei.

Claims 19 and 20 are rejected as obvious over Rapaport, Quelle, and Frei. The rejection should be reversed for the reasons noted above. For example, Rapaport does not teach soya peptide composition for treating stretchmarks. The Office erroneously relied on Frei to remedy this deficiency. Furthermore, the Office erroneously relied on Quelle to teach a tripeptide for treating or reducing the formation of stretchmarks.

CONCLUSION

Applicants respectfully submit that all claims on appeal are allowable. Applicants request reversal of the Examiner's rejection of claims 12, 18-24, 26-32, and 34-44.

Under the provisions of 37 C.F.R. § 41.37, this Appeal Brief is being filed together with a credit card payment form in the amount of \$540.00 covering the 37 C.F.R. 41.20(b)(2) appeal fee. If this fee is deemed to be insufficient, authorization is hereby given to charge any deficiency (or credit any balance) to the undersigned deposit account 19-0741.

Respectfully submitted,

Date: 8-MAR-2010

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By



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VIII. CLAIMS APPENDIX

1. A method for reducing the formation of and/or treating skin stretchmarks in a person, comprising
applying to at least one area of skin comprising one or more stretchmarks a composition comprising, in a suitable vehicle, at least one soya peptide.
2. The method according to claim 1, wherein the soya peptide is obtained by hydrolyzing a protein extracted from soya.
3. The method according to claim 2, wherein the soya peptide is obtained by fermenting the peptide.
4. The method according to claim 3, wherein the soya peptide is obtained by fermenting the peptide with a strain of *Lactobacillus*.
5. The method according to claim 3, wherein the soya peptide has a molecular weight of about 200 daltons to about 20,000 daltons.
6. The method according to claim 3, wherein the soya peptide has a molecular weight of about 800 daltons.
7. The method according to claim 1, wherein the soya peptide is between about 0.1% and about 10% by weight relative to the total weight of the composition.
8. The method according to claim 1, wherein the composition further comprises at least one α -hydroxyacid.
9. The method according to claim 8, wherein the proportion of α -hydroxyacid is between 0.1% and about 20% by weight relative to the total weight of the composition.
10. The method according to claim 8, wherein the α -hydroxyacid is lactic acid.
11. The method according to claim 1, wherein the composition further comprises a compound for adjusting the pH to a value of between about 2 and about 4.

12. A method for reducing the formation of and/or treating skin stretchmarks in a person, comprising applying to at least one area of skin comprising one or more stretchmarks a composition comprising, in a suitable vehicle, at least one tripeptide consisting essentially of the amino residues glycine, histidine, and lysine.
13. A method for reducing the formation of and/or treating skin stretchmarks in a person, comprising applying to at least one area of skin comprising one or more stretchmarks and/or an at least one area liable to form stretchmarks, a composition comprising, in a suitable vehicle, at least one tripeptide having the sequence Gly-His-Lys, and the tripeptide is conjugated with acetic acid or acetate in the form of a complex with zinc.
14. The method according to claim 13, wherein the tripeptide is between about 0.1% and about 10% by weight relative to the total weight of the composition.
15. The method according to claim 13, wherein the composition further comprises at least one α -hydroxyacid.
16. The method according to claim 15, wherein the proportion of α -hydroxyacid is between 0.1% and about 20% by weight relative to the total weight of the composition.
17. The method according to claim 13, wherein the composition further comprises lactic acid.
18. The method according to claim 13, wherein the composition further comprises a compound for adjusting the pH to a value of between about 2 and about 4.
19. A method for reducing the formation of and/or treating skin stretchmarks in a person, comprising applying a composition to areas of skin liable to form stretchmarks or having stretchmarks, the composition comprising, in a suitable vehicle, a mixture of at least one soya peptide and at least one tripeptide selected from tripeptides wherein the tripeptide has the sequence Gly-His-Lys, and the tripeptide is conjugated with acetic acid or acetate in the form of a complex with zinc.
20. A method for reducing the formation of and/or treating skin stretchmarks in a person, comprising applying to at least one area of skin comprising one or more stretchmarks and/or an at least one area liable to form stretchmarks, a composition comprising, in a

suitable vehicle, at least one soya peptide and at least one tripeptide consisting essentially of the amino residues glycine, histidine, and lysine.

21. The method of claim 1, wherein the one or more stretchmarks are a result selected from puberty, pregnancy, a gain in weight and mechanical stress.

22. The method of claim 1, wherein the at least one area of skin is selected from skin of thighs, skin of abdomen, skin of breast and combinations thereof.

23. The method of claim 12, wherein the one or more stretchmarks are a result selected from puberty, pregnancy, a gain in weight and mechanical stress.

24. The method of claim 12, wherein the at least one area of skin is selected from skin of thighs, skin of abdomen, skin of breast and combinations thereof.

IX. EVIDENCE APPENDIX

Declaration Under 37 C.F.R. § 1.132 executed by inventor Philippe Msika on November 12, 2008 and filed and entered in the record on November 14, 2008.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Philippe MSIKA
Title: COSMETIC METHOD FOR PREVENTING AND/OR
TREATING SKIN STRETCHMARKS, AND USE IN
DERMATOLOGY
Appl. No.: 10/808,701
Filing Date: 3/25/2004
Examiner: Gina C. YU
Art Unit: 1617
Confirmation
Number: 6071

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Philippe Msika, being duly warned, hereby declare and state:

1. I understand English when it is written.
2. I was awarded a Ph.D. degree in cutaneous biology from university of Paris, France in 1986 and a Pharmacist Doctorate from university Tours, France in 1988. I am currently employed as head of Innovation, Research and Development at Laboratoires Expanscience where I have been employed since 1996. I have been conducting research and development in the fields of cosmetology and dermatology for more than 20 years.

3. I am the inventor of the invention disclosed and claimed in U.S. Patent Application No. 10/808,701 titled Cosmetic Method For Preventing And/Or Treating Skin Stretchmarks, And Use In Dermatology.

4. I have carefully reviewed U.S. Patent No. 5,444,091 to Rapaport et al. ("Rapaport") and Frei et al., International Journal of Cosmetic Science, 20, 159-173 (1998) ("Frei").

5. In my opinion, a person of ordinary skill in the art would not conclude from Rapaport that stretchmarks (*striae distensae*) are treated by promoting the rigidity and elasticity of the skin. Rapaport speculates that alpha hydroxy acids reduce stretch marks by (i) eliciting a hyperplastic response in the epidermis and dermis that counters the breakdown of collagen, or (ii) by stimulating the production of interfibrillary material such as glycosaminoglycans which promotes both rigidity and elasticity to the skin. See Rapaport column 4, lines 31-38. Rapaport contains no test data supporting these assertions. These proposed mechanisms in Rapaport for enhancing skin elasticity and rigidity are unsupported. Consequently, a person of ordinary skill in the art would consider these mechanisms to be speculative and unproven.

6. Frei provides no basis to infer that soya peptide increases skin firmness, elasticity, and tone. Frei does not directly state that soya peptide increases skin firmness, elasticity, and tone. Frei describes a skin equivalent (SE) model, but Frei lacks any objective measurement of skin firmness, elasticity, and tone. Frei states "the application of soya peptide ... might ... delay the in vitro process of aging." Frei, p. 171, 3d full para., last sentence (emphasis added). Frei further states "[t]his peptide is able to stimulate regeneration of metabolic activity, which may help the skin to look younger," Frei, p. 171, 4th full para., last sentence (emphasis added). The use of "might" and "may" in the sentences quoted above indicates that the authors were uncertain of these assertions.

7. Frei is equivocal about soya peptide's effect on ageing and recognizes that no definite conclusion is possible. Frei states "no conclusion could be drawn concerning the way

the soya peptide acts in this SE model.” Frei, p. 171, first full paragraph, final sentence. In my opinion, a person of ordinary skill in the art reading Frei would not conclude that soya peptide increases skin firmness, elasticity, and tone.

8. A person of ordinary skill in the art reading Frei and Rapaport would not conclude that a soya peptide would be effective for treating stretchmarks. Frei states, “In this model, the soya peptide increased the thickness of the epidermis.” See Abstract. While that effect may support anti-ageing properties, a person of ordinary skill in the art would not recognize effectiveness for treating stretchmarks.

9. Rapaport and Frei relate to nonanalogous fields. Rapaport relates to treating striae distensae, while Frei relates to treating ageing skin (see respective Abstracts of Rapaport and Frei).

10. Striae distensae and skin ageing are unrelated conditions.

11. Most of the formulas on the market dedicated to the treatment of stretchmarks do not contain anti-ageing ingredients.

12. Frei is not reasonably pertinent to the problem that Rapaport seeks to solve. Generally, the problems relating to ageing skin are not the same as the problems reflected in stretchmarks (striae distensae), as noted above.

13. A person of ordinary skill in the art would not conclude that a formulation that is effective for treating the effects of ageing in skin would also be effective in treating stretchmarks (striae distensae).

14. I arrived at the preceding opinions in part because skin ageing and striae distensae have different etiologies, and the physicochemical attributes of ageing skin are different from those for stretchmarks.

15. Stretchmarks appear in 50 to 70 % of the pregnant women, whereas ageing is not limited to the pregnant population.

16. The localization of the two conditions skin ageing and striae distensae differs: Stretchmarks appear on the hip, the breasts, and the buttocks, while ageing appears on the entire skin, but especially on the face and the hands.

17. The appearance of the two conditions differs. Stretchmarks appear as a red or white deep scar which never disappear, while wrinkles have a different appearance.

18. The risk factors of the two conditions differ. For stretchmarks, risk factors include heredity, age (young women), height and weight. Skin ageing does not concern young people, and body weight is not a parameter.

19. The etiologies of skin ageing and striae distensae differ greatly. For striae distensae, biomechanical distension and hormonal (cortisol) impregnation plus inflammation which modify fibroblast phenotype (limitation of the production of collagen and elastin, modification of the type of protein secreted, and alteration of the structure) versus, for skin ageing, a chronological action upregulated by the sun or menopause (no inflammation at all in the natural and the hormonal ageing, no modification of the phenotype of cells, a destruction of the protein).

20. Due to the complicated etiology, a product that stimulates collagen synthesis and elasticity of the skin is not sufficient to prevent or treat stretchmarks.

21. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent resulting therefrom.

08/11/12
Date


Philippe Msika

X. RELATED PROCEEDINGS APPENDIX

None.